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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,684	08/05/2003	Thaddeus J. Mielnik	MEDZ 2 01312	7138
7590 05/31/2007 Thomas E. Kcovsky, Jr. FAY, SHARPE, FAGAN, MINNICH & McKEE, LLP Seventh Floor 1100 Superior Avenue Cleeland, OH 44114-2518			EXAMINER JOYNER, KEVIN	
			ART UNIT 1744	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,684	MIELNIK ET AL.	
	Examiner	Art Unit	
	Kevin C. Joyner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 4-7, 10-13, 15 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Adamski (DE Publication No. 19537630 A1).

Concerning claims 1 and 6, Ryan discloses a method for handling mailed items (concerning claim 15) potentially contaminated with a pathogenic agent comprising:

Sorting the potentially contaminated items in an enclosure (12); and

Treating at least a portion of the sorted items with a first decontaminant comprising an oxidizing gas (concerning claim 2; column 7, lines 1-5) capable of destroying the pathogenic agent in a chamber (13) which is selectively connected with the enclosure and is isolatable from the enclosure as disclosed in columns 6 & 7, lines 56-68 & 1-55 as well as column 8, lines 28-37 respectively. Ryan does not appear to disclose treating the enclosure with a second decontaminant. However, it is known in the art of sterilization to treat an enclosure where potentially pathogenic items are being sorted with a decontaminant in order to reduce the potential for the contaminated items to contaminate clean items or even operators that may come in contact with the

Art Unit: 1744

enclosure at any given time. One such example is disclosed by Adamski wherein the reference discloses a method for handling items potentially contaminated with a pathogenic agent comprising sorting the potentially contaminated items in an enclosure (page 1, paragraphs 1-3); treating at least a portion of the items with a decontaminant capable of destroying a pathogenic agent and treating the enclosure with a decontaminant after the items have been removed from the enclosure (concerning claim 37) comprising an antimicrobial vapor of hydrogen peroxide (concerning claims 4 and 5) as disclosed in paragraphs 4-6. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ryan to include treating the enclosure with a decontaminant vapor comprising hydrogen peroxide in order to reduce the potential for the contaminated items to contaminate clean items or even operators that may come in contact with the enclosure at any given time as exemplified by Adamski.

Concerning claim 7, Ryan continues to disclose that prior to the step of treating at least a portion of the items with a first decontaminant:

Transporting the at least a portion of the items from the enclosure to the chamber connected with the enclosure; and

Closing off the chamber from the enclosure (column 7, lines 35-38; column 7, lines 45-55; column 8, lines 30-37). Regarding claim 10, the reference continues to disclose that the enclosure is operated under a negative pressure. As disclosed in column 7, lines 33 and 34, the enclosure is in a sanitization room that is operated under negative pressure, therefore it is operated under a negative pressure.

In regards to claim 11, Ryan continues to disclose that the step of sorting includes using manipulators to sort the items; and placing the items to be decontaminated with the first decontaminant in a basket (column 11, lines 4-10; column 12, lines 40-56; column 11-29). More specifically, the enclosure (referenced as a singulator; column 12, lines 9-11) sorts the items using manipulators and places the items in a sort bin (column 12, lines 40-56), which is a bucket (a known equivalent alternative to a basket) as disclosed in column 11 lines 4-10, that are to be decontaminated with the first decontaminant (column 13, lines 10-26) as shown in Figure 9c.

Concerning claims 12 and 13, the reference also discloses loading the at least a portion of the items into a basket (as discussed in the previous paragraph); transporting the basket into the chamber of a sterilizer connected with the enclosure (column 13, lines 11-20); evacuating the sterilizer chamber; and introducing gaseous sterilant to the chamber, the items being kept in the sterilizer for a sufficient time to decontaminate the items (column 7, lines 1-8). More specifically, the chamber (13) is kept in a sanitization room that is kept under a continuous negative pressure, therefore it is operated under a negative pressure that would evacuate and aerate the chamber. Furthermore, as the sterilant is added to the chamber, the constant negative pressure will remove the sterilant from the chamber. Once the sterilant is no longer being introduced, the negative pressure will remove the residual sterilant in the chamber and provide a constant flow of air into the chamber because it is not operated in an airtight manner.

Art Unit: 1744

Regarding claim 38, Ryan continues to disclose that the sorting step is performed prior to treating the sorted items as shown in Figure 5a.

Concerning claim 39, in an alternate embodiment, Ryan discloses that the sorting step comprises sorting items between, items which are not suited to treatment by the first decontaminant, and items which are suited for treatment by the first decontaminant in column 13, lines 1-27. More specifically, the sorter (referenced as a diverter) comprises sorting the items into two categories wherein one category is sent to the chamber (referenced as a sanitization/processing area) and the other is sent for further processing. Therefore, only the suspected mail items, which are suited for treatment, are sanitized in order to reduce the amount of decontaminant used in the process. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process wherein the sorting step sorts items between items which are not suited to treatment by the first decontaminant and items which are suited for treatment by the first decontaminant in order to reduce the amount of decontaminant used in the process.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Adamski (DE Publication No. 19537630 A1) as applied to claims 1-2, 4-7, 10-13, 15 and 37-39 above, and further in view of Baran (U.S. Patent No. 4,241,010).

Ryan in view of Adamski is relied upon as set forth in reference to claims 1-2, 4-7, 10-13, 15 and 37-39 above. Ryan in view of Adamski does not appear to disclose the oxidizing gas includes ethylene oxide. Baran discloses biocidal gas sterilization

Art Unit: 1744

methods in which ethylene oxide is used to sterilize items (column 1, lines 8-10).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Ryan in view of Adamski to utilize ethylene oxide to sterilize the items, as is a known sterilant against harmful bacteria as exemplified by Baran.

4. Claims 14, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Adamski (DE Publication No. 19537630 A1) as applied to claims 1-2, 4-7, 10-13, 15, and 37-39 above, and further in view of Clark (U.S. Patent No. 4,317,521).

Ryan in view of Adamski is relied upon as set forth in reference to claims 1-2, 4-7, 10-13, 15 and 37-39 above. Ryan in view of Adamski continue to disclose utilizing an x-ray machine in the method to detect a pathogenic agent (column 10, lines 7-25). Ryan in view of Adamski does not appear to disclose that the x-ray machine is within the enclosure. Clark discloses a method of sorting items in an enclosure. The reference further discloses that the enclosure includes an x-ray machine utilized to examine the items within the enclosure as disclosed in columns 3 & 4, lines 15-68 & 1-36, in order to minimize the number of steps in the system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ryan in view of Adamski to examine at least a portion of the items with an x-ray machine within the enclosure in order to minimize the number of steps needed to perform the process as exemplified by Clark. Concerning claim 17, Ryan discloses employing at least one detector (the x-ray machine) capable of detecting at least one

Art Unit: 1744

pathogenic agent when present at a detectable level, wherein at least one step of treating the sorted items with the pathogenic agent is tailored according to the level of pathogenic agent detected or the type of pathogenic agent detected to improve the effectiveness of the step (column 10, lines 8-14; column 7, lines 1-4). Ryan does not appear to disclose that the detector detects the agents within the enclosure. As discussed above, Clark discloses a method of sorting items in an enclosure. The reference further discloses that the enclosure includes an x-ray machine utilized to examine the items within the enclosure as disclosed in columns 3 & 4, lines 15-68 & 1-36, in order to minimize the number of steps in the system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ryan in view of Adamski to detect the agents within the enclosure with the detector in order to minimize the number of steps, and reduce the amount of materials needed to perform the process as exemplified by Clark. Regarding claim 16, Ryan discloses scanning a document in the mail with a scanning device to generate a scanned image; and transmitting the scanned image to a location outside the enclosure (column 10, lines 25-39). More specifically, the x-ray machine produces images and therefore scans the items. Ryan does not appear to disclose scanning a document within the enclosure. As discussed above, Clark discloses a method of sorting items in an enclosure. The reference further discloses that the enclosure includes an x-ray (which is a scanner) machine utilized to examine the items within the enclosure as disclosed in columns 3 & 4, lines 15-68 & 1-36, in order to minimize the number of steps in the system. Therefore, it would have been obvious to one of ordinary skill in the art at

Art Unit: 1744

the time of the invention to modify the method of Ryan in view of Adamski to scan the documents within the enclosure in order to minimize the number of steps, and reduce the amount of materials needed to perform the process as exemplified by Clark.

5. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Adamski (DE Publication No. 19537630 A1) as applied to claims 1-2, 4-7, 10-13, 15 and 37-39 above, and further in view of Folsom et al. (U.S. Patent No. 4,111,753).

Ryan in view of Adamski is relied upon as set forth in reference to claims 1-2, 4-7, 10-13, 15, and 37-39 above. Ryan in view of Adamski does not appear to disclose how the items are introduced to the enclosure. More specifically, that the items are introduced in a sealed container including: connecting the sealed container containing the items with an interlock which selectively provides access to the enclosure while forming a seal between the container and the interlock; with the container connected to the interlock, opening the container to the enclosure; and introducing the items to the enclosure from the container. Folsom discloses an apparatus and method for transferring items to a sealed chamber from a sealed container. The patent continues to disclose that the items are introduced in a sealed container (30) including: connecting the sealed container containing the items with an interlock which selectively provides access to the enclosure while forming a seal between the container and the interlock; with the container connected to the interlock, opening the container to the enclosure; and introducing the items to the enclosure from the container (as disclosed in column 3, lines 53-68 as well as Figures 1, 4, and 8). Therefore, it would have been

Art Unit: 1744

obvious to one of ordinary skill in the art at the time of the invention to include in the method of Ryan in view of Adamski, introducing the items into the enclosure as exemplified by Folsom in order to keep the enclosure from being contaminated by the surroundings as well as to keep the surroundings contamination free from any of the decontaminates located in the enclosure.

6. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Mueller et al. (U.S. Patent No. 5,792,435) and Folsom et al. (U.S. Patent No. 4,111,753).

Ryan discloses a method for handling items potentially contaminated with a pathogenic agent comprising; sorting items within an isolated enclosure (12); transporting the items through an outlet into a decontamination chamber (13); treating the portion of the sorted items in the decontamination chamber with a first decontaminant capable of destroying the pathogenic agent; and while the portion of the sorted items is being treated in the decontamination chamber, receiving and sorting additional items in the isolated enclosure as disclosed in relation to claims 1-2, 4-7, 10-13, 15 and 37-39 (column 7, lines 1-50). More specifically the system of the present works in a continuous fashion wherein the feeder (10) feeds the singulator (12), which sorts the items, and sends them to the sanitizer (13). The sanitizer comprises a transporting means for continuously transporting the items to the clean room (42) for further processing. Therefore, while a portion of the sorted items are being treated in the decontamination chamber (13), the enclosure is receiving additional items. Ryan does not appear to disclose the steps wherein; an outlet door is

Art Unit: 1744

opened that is located between the enclosure and an isolated region; the sorted items are moved through the outlet door into a sealable decontamination chamber; and sealing the decontamination chamber from the enclosure.

Mueller discloses a method for handling items potentially contaminated with a pathogenic agent comprising:

Transporting the items in a container (column 4, lines 1-10);

Connecting the container to an isolated enclosure (14);

Using manipulators to manipulate the items in the containers within the isolated enclosure (column 3, lines 40-47)

Opening an outlet door between the isolated enclosure and an isolated region;

Moving at least a portion of the items through the outlet door and the isolated region into a sealable decontamination chamber (14'); and

Sealing the decontamination chamber from the enclosure; and

Treating the portion of the sorted items in the decontamination chamber with a first decontaminant capable of destroying the pathogenic agent as disclosed in Figure 3, and column 5, lines 24-63. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ryan to utilize the airtight enclosure and chamber of Mueller in order to reduce the risk of contaminating unnecessary areas throughout the process as exemplified by Mueller.

Ryan in view of Muller do not appear to disclose; transporting the items in a sealed container; connecting the sealed container to an isolated enclosure in an airtight manner; or using manipulators, opening the container to an interior of the

Art Unit: 1744

enclosure, and removing the items from the container into the enclosure. Folsom discloses an apparatus and method for transferring items to a sealed chamber from a sealed container. The method continues to disclose that; the items are transported in a sealed container (30); the sealed container is connected to an isolated enclosure in an airtight manner; and using manipulators, the container is opened to an interior of the enclosure, wherein the items are removed from the container into the enclosure (column 3, lines 42-68 as well as Figures 1, 4, and 8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Ryan in view of Mueller, transporting the items in a sealed container, connecting the sealed container in an airtight manner, and using manipulators to open the container into the interior of the enclosure in order to remove all possibilities of contaminating the outside environment to pathogenic agents as exemplified by Folsom. Concerning claim 32, Ryan continues to disclose that after treating the portion of the sorted items in the decontamination chamber, removing the treated items directly to atmosphere without going through the enclosure as shown by the arrows in Figure 5a.

7. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Mueller et al. (U.S. Patent No. 5,792,435) and Folsom et al. (U.S. Patent No. 4,111,753) as applied to claims 31 and 32 above, and further in view of Adamski (DE Publication No. 19537630 A1).

Ryan in view of Mueller and Folsom are relied upon as set forth above. Ryan in view of Mueller and Folsom do not appear to disclose treating the enclosure with a

Art Unit: 1744

second decontaminant. However, it is known in the art of sterilization to treat an enclosure where potentially pathogenic items are being sorted with a decontaminant in order to reduce the potential for the contaminated items to contaminate clean items or even operators that may come in contact with the enclosure at any given time. One such example is disclosed by Adamski wherein the reference discloses a method for handling items potentially contaminated with a pathogenic agent comprising sorting the potentially contaminated items in an enclosure (page 1, paragraphs 1-3); treating at least a portion of the items with a decontaminant capable of destroying a pathogenic agent and treating the enclosure with a decontaminant comprising an antimicrobial vapor of hydrogen peroxide after the items have been removed (concerning claims 4 and 5) as disclosed in paragraphs 4-6. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Ryan in view of Mueller and Folsom to include treating the enclosure with a decontaminant vapor comprising hydrogen peroxide in order to reduce the potential for the contaminated items to contaminate clean items or even operators that may come in contact with the enclosure at any given time as exemplified by Adamski.

8. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan Jr. et al. (U.S. Patent No. 7,071,437) in view of Mueller et al. (U.S. Patent No. 5,792,435), Folsom et al. (U.S. Patent No. 4,111,753) and Adamski (DE Publication No. 19537630 A1) as applied to claims 31-34 above, and further in view of Baran (U.S. Patent No. 4,241,010).

Ryan in view of Mueller, Folsom, and Adamski are relied upon as set forth above. Ryan continues to disclose wherein treating the portion of the sorted items in the decontamination chamber includes: evacuating the decontamination chamber; introducing a gaseous vapor; removing the vapor from the chamber; and aerating the sorted items in the decontamination chamber to remove absorbed vapor as referenced with respect to claims 12 and 13. Ryan in view of Mueller, Folsom and Adamski does not appear to disclose that the gaseous vapor is ethylene oxide. Baran discloses biocidal gas sterilization methods in which ethylene oxide is used to sterilize items (column 1, lines 8-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Ryan in view of Mueller, Folsom and Adamski using ethylene oxide to sterilize items as is a known sterilant against harmful bacteria as exemplified by Baran. Regarding claim 36, Baran continues to disclose that the decontaminant used to treat the enclosure includes hydrogen peroxide as referenced with respect to claim 5.

Response to Arguments

9. Applicant's arguments, see pages 7-10, filed March 19, 2007, with respect to the rejection(s) of claim(s) 1-18 under 35 U.S.C 102(e) and 35 U.S.C 103(a) respectively have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the newly found prior art references of Ryan (U.S. Patent No. 7,071,437),

Art Unit: 1744

Adamski (DE Publication No. 19537630), Mueller (U.S. Patent No. 5,792,435), Folsom (U.S. Patent No. 4,111,753), Baran (U.S. Patent No. 4,241,010), and Clark (U.S. Patent No. 4,317,521). Further explanation is set forth above with regard to the rejections on claims 1-18.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER

Application/Control Number: 10/634,684
Art Unit: 1744

Page 15

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